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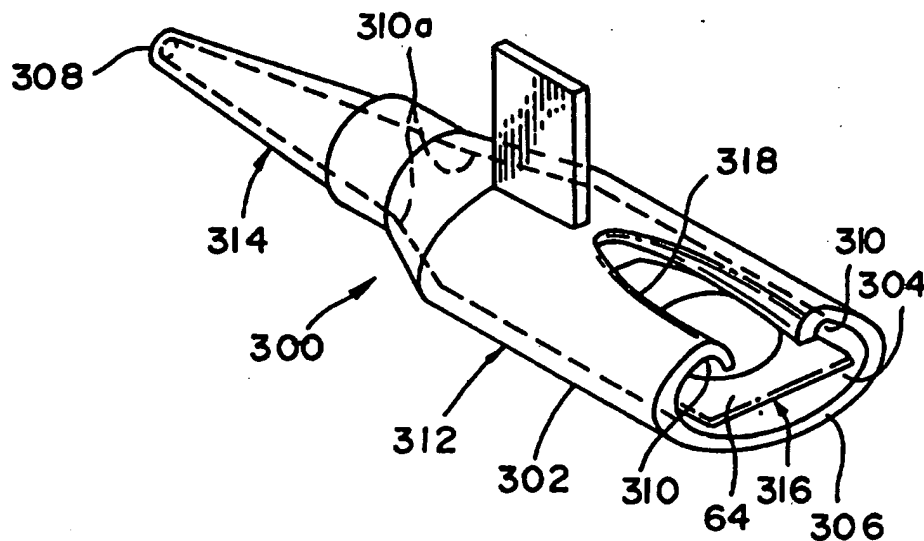


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: <b>A61F 9/00</b>	<b>A1</b>	(11) International Publication Number: <b>WO 96/20662</b>
		(43) International Publication Date: 11 July 1996 (11.07.96)
(21) International Application Number: PCT/US96/00264		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AZ, BY, KZ, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 4 January 1996 (04.01.96)		
(30) Priority Data: 08/368,792 4 January 1995 (04.01.95) US		
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Published  
With international search report.

(54) Title: A METHOD AND APPARATUS FOR FOLDING A DEFORMABLE INTRAOCULAR LENS



(57) Abstract

An intraocular lens injection system and method of injecting an intraocular lens. The intraocular lens injection system includes an injecting device with a converging passageway (416), and grooves (410) for curling the ends of the deformable intraocular lens (64) into a folded position prior to insertion into the eye.

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## A METHOD AND APPARATUS FOR FOLDING A DEFORMABLE INTRAOCULAR LENS

### RELATED APPLICATIONS

This is a Continuation-In-Part of U.S. patent application entitled "HINGELESS  
5 INTRAOCULAR LENS MICROCARTRIDGES", Serial No. 08/196,855, filed on  
February 15, 1994, which is a Continuation-In-Part of U.S. patent application entitled  
"INTRAOCULAR LENS INSERTION SYSTEM, Serial No. 07/953,251, filed on  
September 30, 1992, now abandoned, both fully incorporated by reference herein.

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### FIELD OF THE INVENTION

This invention relates to systems and methods for the injection of deformable  
intraocular lens into the eye. Specifically, the present invention relates to injecting  
devices, cartridges, and methods of inserting deformable intraocular lens into the eye.

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### BACKGROUND OF THE INVENTION

Intraocular lenses have gained wide acceptance in replacement of human  
crystalline lenses after a variety of cataract removal procedures. The human crystalline  
20 lens is generally recognized to be a transparent structure having a thickness of about

five (5) millimeters and a diameter of about nine (9) millimeters. The lens is suspended behind the iris by zonula fibers which connect the lens to the ciliary body. A lens capsule surrounds the lens, the front portion of the capsule being commonly known as the anterior capsule and the back portion commonly known as the posterior capsule.

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Numerous procedures for the removal of cataracts have been developed in which the lens is removed from the eye and replaced by an artificial lens implant. The extraction procedure may generally be categorized as intracapsular (in which the lens is removed together with the lens capsule) and extracapsular (in which the anterior capsule is removed with the lens, and the posterior capsule is left intact).

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Since Ridley implanted the first artificial lens in about 1949, the problems associated with cataract extraction and lens implantation have received a great deal of attention from ophthalmic surgeons. Various types of artificial lenses have been proposed, and appropriate surgical procedures have been developed which strive to reduce patient discomfort and to reduce postoperative complications. Reference is made in this connection to Pseudophakos by N. Jaffe et al.; "History of Intraocular Implants" by D.P. Choyce (Annals of Ophthalmology, October 1973); U.S. Patent No. 4,251,887 issued to Anis on February 24, 1981; U.S. Patent No. 4,092,743 issued to Kelman on November 8, 1977; "Comparison of Flexible Posterior Chamber Implants", presented at the American Intraocular Implant Society Symposium April 23, 1982, by

Charles Berkert, M.D.; and "the Simcoe Posterior Lens" (Cilco, Inc. 1980); U.S. Patent No. 4,573,998 issued to Mazzocco on March 4, 1986, and U.S. patent application Ser. No. 400,665 for "Improved Fixation System for Intraocular Lens Structures", filed July 22, 1982, U.S. Patent No. 4,702,244 issued to Mazzocco on  
5 October 27, 1987; and U.S. Patent No. 4,715,373 issued to Mazzocco et al. on December 29, 1987, which disclosures are hereby incorporated by reference.

Of particular interest in the context of the present invention is the development of surgical techniques requiring relatively small incisions in the ocular tissue for the  
10 removal of cataracts as disclosed in U.S. Patent No. 4,002,169 and U.S. Patent No. 3,996,935. A number of skilled artisans have disclosed intraocular lens structures comprising an optical zone portion generally made of rigid materials such as glass or plastics suitable for optical use.

15 However, one of the principal disadvantages of the conventional rigid intraocular lens is that implantation of the lens requires large incisions in the ocular tissue. This type of surgical procedure leads to a relatively high complication rate, among other disadvantages. For instance, the serious dangers associated with implantation of a rigid lens structure include increased risk of infection, retinal  
20 detachment, and laceration of the ocular tissue, particularly with respect to the pupil.

Accordingly, those skilled in the art have recognized a significant need for surgical tools for implantation of deformable intraocular lens structures which afford the clinical advantages of using relatively small incision techniques, which provide a safer and more convenient surgical procedure. In particular, those skilled in the art of deformable intraocular lenses and methods and devices for implantation, have also recognized a significant need for surgical tools which do not require widening of the wound made in the ocular tissue during or after implantation, but will deform the intraocular lens to a predetermined cross section in a stressed state and which allow the ophthalmic surgeon to inspect the lens prior to implantation without manipulation in the eye. The present invention fulfills these needs.

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The present invention was derived by improving the methods and devices in the above-identified patents, specifically the methods of U.S. Patent No. 4,573,998 and the devices of U.S. Patent No. 4,702,244.

U.S. Patent 5,275,604 to Rheinisch et al. is particularly relevant with respect to some of the inventions disclosed herein. U.S. Patent 5,275,604 is wholly incorporated by reference herein.

## SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved intraocular lens microcartridge.

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Another object of the present invention is to provide a intraocular lens microcartridge for use with a surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, said lens microcartridge comprising a lens holder portion having a lens receiving  
10 portion for receiving and holding the deformable intraocular lens, and a nozzle portion connected to and extending from said lens holder portion, said lens holder portion and said nozzle portion having a continuous passageway extending therethrough.

A further object of the present invention is to provide an intraocular lens  
15 microcartridge with a hingeless construction.

An even further object of the present invention is to provide an intraocular lens microcartridge having a lens receiving portion that is fixed relative to a nozzle portion thereof.

20

Another further object of the present invention is to provide an intraocular lens microcartridge with a lens receiving portion having an oval shaped barrel configuration.

Another object of the present invention is to provide an intraocular lens  
5 microcartridge having a lens receiving portion provided with a longitudinal slot therethrough to allow a deformable intraocular lens to be loaded through the slot.

A further object of the present invention is to provide an intraocular lens microcartridge having a lens receiving portion provided with a longitudinal slot  
10 therethrough and extending to an end of a lens holder portion to allow a deformable intraocular lens to be loaded through the slot.

An even further object of the present invention is to provide an intraocular lens microcartridge having a lens receiving portion provided with a longitudinal slot  
15 therethrough and extending from a rounded end to an end of a lens holder portion to allow a deformable intraocular lens to be loaded through the slot.

Another further object of the present invention is to provide an intraocular lens microcartridge with a lens holder portion including a transition portion with an oval  
20 shaped barrel located between a lens receiving portion and a nozzle portion.



Another object of the present invention is to provide an intraocular lens microcartridge with a lens holder portion including a transition portion with an oval shaped barrel defined by inwardly tapering side walls that taper from the dimensions of the lens receiving portion to the dimensions of the nozzle portion located between  
5 a lens receiving portion and a nozzle portion.

A further object of the present invention is to provide an intraocular lens microcartridge with a lens receiving portion provided with an oval shaped barrel, a transition portion provided with an oval shape barrel with inwardly tapering sides, and  
10 a nozzle portion provided with an inwardly tapering conical passageway defining a continuous passageway through the microcartridge.

An even further object of the present invention is to provide an intraocular lens microcartridge with an oval shaped barrel of a transition portion defined by conical  
15 shaped inner side walls, a substantially flat bottom wall, and a top wall having a downwardly extending protrusions that tapers so as to become less pronounced when extending from a lens receiving portion to a nozzle portion.

Another further object of the present invention is to provide an intraocular lens  
20 microcartridge with an oval shaped barrel of a transition portion defined by conical shaped inner side walls, a substantially flat bottom wall, and a top wall having a downwardly extending protrusion that tapers so as to become less pronounced when

extending from a lens receiving portion to a nozzle portion wherein the inner top wall is substantially parallel to the inner bottom wall.

Another object of the present invention is to provide an intraocular lens microcartridge having an oval shaped barrel in a receiving portion having greater cross-sectional dimensions relative to cross-sectional dimensions of an entranceway into a nozzle portion thereof.

A further object of the present invention is to provide a intraocular lens microcartridge for use with a surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, the lens microcartridge comprising a lens holder portion having a lens receiving portion for receiving and holding the deformable intraocular lens, and a nozzle portion connected to and extending from said lens holder portion and having a tapering configuration, the lens holder portion and the nozzle portion having a continuous passageway extending therethrough.

An even further object of the present invention is to provide an intraocular lens microcartridge having an outer wall of a nozzle portion tapering downwardly from a lens holder portion to a free end of the nozzle portion.

Another further object of the present invention is to provide an intraocular lens microcartridge having an inner wall and an outer wall of a nozzle portion tapering together in a direction towards a free end of the nozzle portion providing a wall thickness that tapers thinner from the lens holder portion to the free end of the nozzle portion.

Another object of the present invention is to provide an intraocular lens microcartridge having an extension of the lens microcartridge for aligning the lens microcartridge in a surgical device for implantation of the deformable intraocular lens.

A further object of the present invention is to provide an intraocular lens microcartridge having an extension of the lens microcartridge for aligning the lens microcartridge in a surgical device for implantation of the deformable intraocular lens wherein the extension protrudes upwardly from the lens holder portion.

An even further object of the present invention is to provide an intraocular lens microcartridge for use with a surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, the lens microcartridge comprising a lens holder portion having a lens receiving portion defined by a cylinder having a longitudinal slot therethrough for receiving and holding the deformable intraocular lens, the lens holder having a transition portion defined by a tapering inwardly interior wall extending from said lens receiving portion,

a nozzle portion connected to and extending from the transition portion of the lens holder portion, the lens holder portion and the nozzle portion having a continuous passageway extending therethrough, and an extension of the lens holder portion for aligning the lens microcartridge in the device for implantation of the deformable  
5 intraocular lens.

Another object of the present invention is to provide a cartridge having a pair of opposed converging grooves for folding the intraocular lens.

10 A further object of the present invention is to provide a cartridge having a configuration to accept the intraocular lens in a flat configuration with a pair of opposed converging grooves for folding the intraocular lens.

An even further object of the present invention is to provide a cartridge having  
15 a funnel-type configuration for further folding the intraocular lens.

Another even further object of the present invention is to provide a cartridge having a funnel-type configuration with a pair of opposed converging grooves for further folding the intraocular lens.

20

The present invention is directed to methods and devices for implantation of intraocular lenses into the eye. In particular, the present invention is directed to hingeless type intraocular lens microcartridges.

5           A surgical device according to the present invention includes the combination of a lens holder and a holder for the lens holder or lens microcartridge. The preferred lens microcartridge comprises the combination of a lens receiver and an implantation nozzle. The lens receiver in one preferred embodiment is defined by a split tubular member having a fixed tubular portion with an extension connected to a moveable  
10           tubular portion with an extension at a hinge. This configuration allows the microcartridge to be opened to accept a deformable intraocular lens, and closed to condense the lens into the passageway. The split tubular portion is connected to a nozzle with a continuous passageway passing through the tubular member and the nozzle.

15

Another preferred embodiment is a hingeless type microcartridge into which a lens is carefully loaded prior to being placed in the receiver of the surgical implantation device.

20

The lens holder is inserted into a holder (i.e. surgical implantation device) having means for driving or manipulating the lens from the lens holder into the eye. In the preferred embodiment, the holder is provided with a plunger for driving the lens

from the lens holder into the eye. Further, the holder is configured to receive the microcartridge having a nozzle of the hinged or hingeless version.

5 The preferred holder includes means to prevent the microcartridge from rotating within the holder, and means for preventing the plunger from rotating within the holder. The means for preventing rotation of the microcartridge within the holder can be define by providing the microcartridge with one or more extensions that cooperate with the opening of the receiver of the holder to prevent rotation. The means for preventing the plunger from rotating within the holder can be defined by providing the  
10 plunger and a sleeve within the holder with a particular cross-sectional shape that prevents rotation, for example, a half-circle shape.

The preferred holder includes a plunger with a threaded cap cooperating with a threaded sleeve of the holder body for dialing the plunger forward within the holder  
15 for precise and accurate movement of the lens during the implantation process. The holder is configured so that the plunger can be moved a predetermined distance by sliding motion within the holder body followed by engagement of the threaded cap of the plunger with the threaded sleeve of the holder body to continue the forward progress of the plunger tip.

20

The preferred plunger tip is defined by a faceted tip having various surfaces for moving and manipulating the lens from the lens holder and within the eye. The tip is

designed to provide a clearance between the tip and the inner surface of the passageway through lens holder to accommodate the trailing haptic and prevent damage thereto. Once the lens is inserted into the eye, the tip can be used to push and rotated the lens into proper position within the eye.

5

A method according to the present invention includes lubricating the surface of a deformable intraocular lens with a surgically compatible lubricant, and loading the lens into a microcartridge in the opened position. The microcartridge is closed while condensing the lens by a folding action into a shape so that it can be forced through the  
10 passageway in the microcartridge. The microcartridge is inserted into the holder with the plunger retracted.

The plunger is moved forward in a sliding manner by pushing the plunger forward while holding the holder body still. This action forces the lens from the  
15 tubular member portion of the microcartridge into the nozzle portion. At this point the threads of the threaded end cap of the plunger engage with the threads of the threaded sleeve. The threaded end cap is rotate slightly to engage the threads. The device is now ready for the implantation process.

20

The nozzle of the microcartridge is placed through a small incision in the eye. The threaded end cap of the plunger is rotated or dialed to further advance the lens forward through the nozzle and into the eye. The threaded end cap is further dialed

to exposed the tip of the plunger within the eye and push the lens into position. The tip can be used to also rotate the lens within the eye for positioning of the haptics.

Another preferred embodiment of the cartridge according to the present invention is specifically configured to fold an intraocular lens that is initially loaded flat into the cartridge. This cartridge allows an intraocular lens to be potentially stored flat in the cartridge during shipment from the manufacturing facility to distributors and end users. Alternatively, an end user can simply load a packaged intraocular lens into the cartridge just prior to use or in preparation for the surgical procedure.

10

The cartridge includes a passageway defined by a set of opposed grooves that converge together folding the edges of the lens until the lens is sufficiently folded to pass through the nozzle portion of the cartridge. The tapering or converging nature of the passageway is preferably continuous so as to prevent any damage to the lens as it moves through the cartridge. In some embodiments, the grooves in the passageway converges along a portion of the length of the passageway, and in other embodiments the grooves converge along the entire length of the passageway through the lens holding portion and the nozzle portion of the cartridge. For example, in one embodiment, the grooves initially remain of constant size and cross-sectional shape until a transition portion of the passageway through the lens holding portion where the grooves converge folding the edges of the lens to a sufficient degree to allow the lens to pass through the passageway in the nozzle portion.

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A further embodiment of the cartridge according to the present invention has a funnel-like construction wherein the passageway through the cartridge is funnel shaped to further fold the lens as it is moved through the cartridge. The cartridge can be provided with a set of opposed grooves located above a horizontal center plane of the cartridge that further fold the edges towards each other until the lens is fully folded to an extent to allow the lens to pass through the passageway of the nozzle portion. A preferred embodiment of the funnel-type cartridge is defined by an essentially an oval-cross-sectional passageway that converges in a direction towards the nozzle portion. The oval shaped passageway is oriented so that the major axis is substantially aligned with center plane of the lens.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a perspective view of one embodiment of device according to the present invention with a lens holding microcartridge positioned in the device for implantation of deformable lens structures for placement in the eye;

Figure 2 is a perspective view of the surgical device depicted in Figure 1 with the plunger retracted, and with the lens holding microcartridge removed;

Figure 3 is a side view of the device depicted in Figure 2, with the plunger in the extended position;

Figure 4 is a side elevational view of the device shown in Figure 1;

Figure 5 is a detailed longitudinal cross-sectional view of the device shown in Figure 4;

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Figure 6 is a detailed transverse cross-sectional view of the device, as indicated in Figure 5;

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Figure 7 is a detailed end view of the device, as indicated in Figure 5;

Figure 8 is an enlarged detailed left side elevational view of the tip of the plunger in the spacial orientation as shown in Figure 1;

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Figure 9 is an enlarged detailed end view of the tip shown in Figure 8;

Figure 10 is an enlarged detailed top planar view of the tip of the plunger;

20

Figure 11 is an enlarged detailed right side elevational view of the tip of the plunger in the spacial orientation, as shown in Figure 4;

Figure 12 is an enlarged detailed bottom view of the tip of the plunger in the spacial orientation, as shown in Figure 1;

Figure 13 is a perspective view of a lens for use in the present invention;

Figure 14 is a perspective view of another type of lens for use in the present invention;

5

Figure 15 is a side view of the lens shown in Figure 13;

Figure 16 is a perspective view of the lens holding microcartridge in the open position to allow a lens to be loaded therein;

10

Figure 16A is another perspective view of the lens holding microcartridge in the open position;

Figure 17 is a rear end elevational view of the lens holding microcartridge in the open position;

15

Figure 18 is a front end elevational view of the lens holding microcartridge in the open position;

Figure 19 is a rear end elevational view of the lens holding microcartridge in the closed position;

20

Figure 20 is a front end elevational view of the lens holding microcartridge in the closed position;

Figure 20A is a detailed end view of the nozzle showing three (3) slots of  
5 different length equally spaced about the circumference of the tip;

Figure 20B is a detailed perspective view of the tip showing the three (3) slots of different length;

10 Figure 20C is a detailed side view showing the beveled tip;

Figure 21 is a top planar view of the lens holding microcartridge in the open position;

15 Figure 22 is a side elevational view of the lens holding microcartridge in the closed position;

Figure 23 is a rear end elevational view of the lens holding microcartridge in the closed position;

20

Figure 24 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in the retracted position;

Figure 25 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a partially extended position;

5 Figure 26 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a fully extended position;

Figure 27 is a perspective view showing the device positioning a deformable intraocular lens within the eye;

10 Figure 28 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into position in the eye by the surgical device;

Figure 29 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into a different position in the eye by the surgical device.

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Figure 30 is a side elevational view of an alternative embodiment of the lens holding microcartridge provided with a beveled tip;

20 Figure 31 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in an open position;

Figure 32 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in a closed position;

5           Figure 33A is a front end elevational view of the nozzle of an alternative embodiment of the lens holding microcartridge; and

Figure 33B is a front end elevational view of the nozzle of a further alternative embodiment of the lens holding microcartridge.

10

Figure 34 is a longitudinal cross-sectional view of a preferred embodiment of the hingeless intraocular lens microcartridge according to the present invention.

15           Figure 35 is a top view of the hingeless intraocular lens microcartridge, as shown in Figure 34.

Figure 36 is a partial broken away top view of the hingeless intraocular lens microcartridge, as shown in Figure 35.

20           Figure 37 is a cross-sectional view of the hingeless intraocular lens microcartridge at location 37-37, as shown in Figure 34.

Figure 38 is a cross-sectional view of the hingeless intraocular lens microcartridge as indicated at 38-38, as shown in Figure 34.

5 Figure 39 is a front elevational view of the hingeless intraocular lens microcartridge shown in Figures 34-37.

Figure 40 is a longitudinal cross-sectional view of the hingeless intraocular lens microcartridge, as shown in Figure 34, with an intraocular lens placed on top of the microcartridge ready for insertion therein.

10

Figure 41 is a rear elevational view of the microcartridge, as shown in Figure 40, with the intraocular lens not yet deformed for inserting into the microcartridge.

15 Figure 42 is a rear elevational view of the microcartridge, as shown in Figure 40, with the intraocular lens partial deformed and bent at the center being inserted into the microcartridge.

Figure 43 is a rear elevational view of the microcartridge, as shown in Figure 40, with the intraocular lens fully deformed and inserted inside the microcartridge.

20

Figure 44 is a partial view of an alternative tip portion of the microcartridge having a beveled end.

Figure 45 is a partial view of another alternative tip portion of the microcartridge having a heat deformed tip.

5 Figure 46 is a perspective view of another embodiment of the cartridge according to the present invention allowing for a deformable intraocular lens to be loaded in a flat orientation.

Figure 47 is a top planer view of the cartridge shown in Figure 46.

10 Figure 48 is a rear end elevational view of the cartridge shown in Figure 46.

Figure 49 is a transverse cross-sectional view of the cartridge as indicated in Figure 47.

15 Figure 50 is a transverse cross-sectional view of the cartridge as indicated in Figure 47.

Figure 51 is a transverse cross-sectional view of the cartridge as indicated in Figure 47.

20

Figure 52 is a further preferred embodiment of the cartridge according to the present invention having a funnel-type configuration.



Figure 53 is a transverse cross-sectional view of the cartridge as indicated in Figure 52.

5 Figure 54 is a transverse cross-sectional view of the cartridge as indicated in Figure 52.

Figure 55 is a transverse cross-sectional view of the cartridge as indicated in Figure 52.

10 Figure 56 is a transverse cross-sectional view of the cartridge as indicated in Figure 52.

Figure 57 is a transverse cross-sectional view of the cartridge as indicated in Figure 57.

15

#### **DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

The present invention is directed to a system including methods and devices for implantation of deformable intraocular lens structures for surgical placement in the eye.

20

An inventive device according to the present invention comprises a holder having a receiver, a lens holder that can be removably inserted into the receiver of the

holder, and means such as a moveable plunger disposed within the holder to force and manipulate the lens from the lens holder into the eye.

Preferably, the lens holder is defined by a lens holding microcartridge for  
5 receiving the lens structure. Further, the microcartridge is preferably a structure configured to be opened and closed. The preferred embodiment of the microcartridge receives a lens having prescribed memory characteristics when in the open position, and performs the function of folding or deforming the lens structure into a condensed configuration when being closed. Alternatively, the microcartridge can be a structure  
10 having a passageway defined by a continuous walled annulus, and a lens could be inserted into the passageway from the end of microcartridge by compressing, rolling, folding, or combination of these techniques prior to insertion into the microcartridge.

Once a lens is positioned into the microcartridge, the microcartridge is  
15 positioned into a plunger device. The assembled device maintains the lens in its condensed configuration during insertion into the eye yet permits the deformed lens to return to its original configuration, size and fixed focal length once implanted in the eye, thereby providing a safe, convenient, and comfortable surgical procedure.

20 A preferred embodiment of a deformable intraocular lens implantation device according to the present invention is shown in Figures 1, 2 and 3. The implantation device comprises a microcartridge 12 disposed within a holder 13 comprising a holder

body 14 with a receiver 15, and a moveable plunger 16. In Figure 1, the receiver 15 is defined by an opening 17 through the wall of the holder body 14 of the size and shape shown in Figures 1 and 2. The opening 17 is defined by parallel edges 17a, 17a, which are sufficiently spaced apart to allow the microcartridge 12 to be loaded into the receiver 15 of the holder 13, tapered edges 17b, clamping edges 17c, and stop edge 17d. In Figure 1, the microcartridge 12 is positioned in the receiver 15 between the clamping edges 17c with the plunger extending through the microcartridge 12 in a position, for example, after a lens implantation procedure.

10 In Figure 2, the lens holding microcartridge 12 is shown removed from the holder 13 with the plunger 16 in a retracted position for allowing the microcartridge 12 containing a loaded lens and its haptic to be inserted within the holder 13. In Figure 3, the holder 13 is shown with the plunger 16 in the extended position without the microcartridge 12 for purposes of illustration of the components.

15

The plunger 16 is fitted with a threaded end cap 18 at one end, and fitted with a tip 20 at an opposite end. The threaded end cap 18 is provided with a plurality of grooves 22 to allow a person to tightly grip the cap 18 with his or her finger tips. The threaded end cap 18 is received within a threaded sleeve 24 of the insert holder 14.

20 The threaded end cap 18 can be a separate component attached to the insert holder 13, or integral therewith, as shown in the construction is Figure 5.

The plunger 16 is installed within the holder 13 in a manner to allow the plunger to be reciprocated therein. In the illustrated embodiment, the plunger 16 is supported for sliding movement within the holder 13 by guide 26, as shown in Figures 5 and 6. The outer dimension of the guide 26 is approximately the same size as the inner dimensions of the holder 13 to allow the guide to be inserted within the insert holder. During construction, the guide 26 is inserted within the holder 13, and locked into position by pin 28 inserted into a predrilled hole in both the wall of the holder 13 and guide 26.

10 The cross-sectional shape of the plunger 16 as well as the shape of the inner surface of the guide 26 are approximately a half-circle, as shown in Figure 6. This arrangement prevents the plunger 16 from rotating within the holder 13 to maintain the orientation of the tip 20 relative to the holder 13 during operation.

15 The threaded end cap 18 is connected to the plunger 16 in a manner to allow the threaded end cap 18 to be rotated relative to the plunger 16. For example, the left end of the plunger 16 (Figure 5) is provided with a threaded extension 30, which is secured to the threaded end cap 18 by a nut 32. Specifically, the threaded end cap 18 is manufactured with external threads 34 and a longitudinal center bore 36 that ends on  
20 the right side of the threaded end cap 18 leaving a wall 38.

The wall 38 is provided with a hole slightly larger than the outer diameter of the threaded extension 34 to allow the threaded end cap 18 to freely rotate on the plunger 16 while being secured to the end of the plunger 16. During construction, the nut 32 is inserted through the center bore 36 and threaded onto the extension 30 to  
5 secure the threaded end cap 18 to the plunger 16. A curved cap 40 is press fitted into the end of the center bore 36 to seal the center bore 36 to prevent debris from entering therein during use.

The details of the tip arrangement are shown in Figures 7 to 12. The plunger  
10 16 is manufactured with an extension 42 supporting tip 20. The tip 20 structure provides means for inserting the deformable intraocular lens into the eye and manipulating the lens within the eye after the insertion step. For example, the tip 20 is faceted in the manner shown in the figures. Specifically, the left side of the tip 20 shown in Figure 8 is provided with a flat surface facet 42, conical surface 44, and  
15 cylindrical surface 46. The right side shown in Figure 11 is provided with a concave surface facet 50.

The end face of the tip 20 is designed to push the lens into position once inserted into the eye. For example, the end face is defined by a concave cylindrical  
20 surface 52 shown in Figure 8.

Suitable deformable intraocular lens for use in the present invention are shown in Figures 13 - 15. The deformable intraocular lens 54 shown in Figures 13 and 15 includes a lens body 56 with attachment means defined by a pair of haptics 58 each having one end anchored in the lens portion 56 and a free end for attachment to the eye tissue. The deformable intraocular lens 60 shown in Figure 14 includes a lens body 62 and attachment means defined by a pair of lateral lobes 64 of the lens portion 62.

The details of the preferred lens holding microcartridge 12 are shown in Figures 16 - 20. The microcartridge 12 comprises a split tubular member 66 extending to a continuous tubular member 67 and an implantation nozzle 68. When the microcartridge is in a closed position, a continuous circular or oval passageway of the same diameter extends through the split tubular member 66 through the continuous tubular member 67 and through the implantation nozzle 68. The microcartridge is preferably made of injection molded plastic such as polypropylene. The split tubular member 66 is defined by a fixed portion 70 and a moveable portion 72. The fixed portion 70 is fixed relative to the implantation nozzle 68, and is defined by a tubular portion 74 and extension 72. The moveable portion 72 is moveable relative to the fixed portion 70 for opening and closing the split tubular member 66. The moveable portion 72 is defined by a tubular portion 78 and extension 80. A hinge 82 is provided between the fixed portion 70 and moveable portion 72. The hinge 82 is defined by reducing the thickness of the walls of the tubular portion 74 and 75 at the hinge 82, as shown in Figures 17, 18 and 19. The hinge 82 runs the length of the split

tubular member 66 to allow the extension 76 and 78 to be split apart, or brought together to open and close, respectively, the split tubular member 66.

5 The tubular portion 78 of the moveable portion 72 is provided with a sealing edge 84, which is exposed when the lens holding microcartridge 12 is opened, as shown in Figure 16A, and seals with a similar sealing edge 86 (See Figures 17 and 21) of the continuous tubular member 67 when the lens holding microcartridge is closed.

10 The end of the tip 20 is provided with three (3) equally spaced slots 87a, 87b and 87c of different length provided about the circumference thereof, as shown in Figures 20A and 20B. The slot 87a positioned at the top of the tip 20 is the shortest, slot 87c on the right side of the tip 20 is the longest, and slot 87b on the left side is of medium length. The slots 87a, 87b, 87c cause the lens 54 to rotate as it exits the tip 20.

15

Other embodiments of the microcartridge 12 according to the present invention are shown in Figures 30-33.

20 The microcartridge shown in Figure 30 is provided with a beveled tip 94 to facilitate entry of the tip through the incision in the eye during implantation. The beveled tip 94 can be set at approximately forty-five (45) degrees relative to the passageway through the microcartridge 12.

The embodiment of the microcartridge shown in Figures 31 and 32 is provided with a set of grooves 96 provided inside the passageway therethrough. The grooves accommodate the edges of the lens being loaded into the microcartridge to facilitate bending of the lens. Specifically, the edges of the lens are placed in the grooves 96 to prevent relative slippage of the edges with the inner surface of the passageway through the microcartridge when the microcartridge is being folded into the closed position.

The embodiments of the microcartridge shown in Figures 33A and 33B each have a nozzle 68' having an oval cross-section with slots 87' differently position as shown, respectively, again to facilitate entry through an incision in the eye. Alternatively, the cross-section can be two half circles set apart and connected together rather than oval.

The various features of the microcartridges shown in Figures 16-21 and 30-33 can be used in various combinations to achieved an optimum design for a particular application. However, all of these features are typically considered improvements of the basic combination.

The components of the device 10, except for the microcartridge 12, are preferably fabricated from autoclavable material such as stainless steel or from a disposable rigid plastic such as medical grade ABS or the like.



## HINGELESS INTRAOCULAR LENS MICROCARTRIDGE

A preferred embodiment of the hingeless type intraocular lens microcartridge according to the present invention are shown in Figures 34-43.

5

In this embodiment, the lens microcartridge 200 comprises a lens holder portion 202 and a nozzle portion 204 connected to and extending from one end of the lens holder portion 202. The lens microcartridge is provided with a continuous passageway therethrough that extends from one end of the lens microcartridge to the other end thereof. The lens holder portion 202 includes a receiver portion 206 for receiving a deformable intraocular lens and a transition portion 208, as shown in Figs. 35 and 36.

10

The receiver portion 206 is defined by a tubular member 210 provided with an oval shaped barrel 212 having a longitudinal slot 214 therethrough. The oval shaped barrel 212 has a constant cross section or a gradually reducing cross section throughout the length of the receiver portion 206. Further, the longitudinal slot 214 has a rounded end 216 at one end, and an open end 218 at an opposite end thereof.

15

The transition portion 208 is defined by a tubular member 220 with an oval shaped barrel 222 having a cross section that tapers inwardly from the receiver portion 206 to the nozzle portion 204. Specifically, the sides 224 of oval shaped barrel 222 taper inwardly, as shown in Fig. 36, while the top surfaces 226 (i.e. defining grooves

20

226) and bottom surface 228 of the oval shaped barrel 222 are parallel (i.e. not tapered), as shown in Fig. 34. Further, the top 226 is provided with a downwardly extending protrusion 230 having curved sides that are shaped to turn the edges of the deformable intraocular lens downwardly, as shown in Fig. 37. The protrusion  
5 becomes less pronounced in a direction extending towards the nozzle portion 204, and disappears at the nozzle portion to provide a continuous inner surface and transition from the lens holder 202 portion into the nozzle portion 204.

The grooves 226 in the receiver portion 206, as shown in Figure 38, are defined  
10 by curled upper portions of the receiver portion 206 on either side of the slot 214, and extend continuously to the grooves of the transition portion 208.

The lens microcartridge 200 is provided with an extension 232 for aligning the lens microcartridge 200 in the device for implantation of the intraocular lens.  
15 Specifically, the extension 232 is defined by plastic material that extends from the lens holder portion 202, and is configured to snag fit in the slot of the device for implantation of the intraocular lens. In the embodiment shown in Figs. 34-39, the extension 232 has a rectangular side profile (See Fig. 34) and has a constant thickness (See Fig. 35) along its length.

20

The manner in which the deformable intraocular lens is inserted into the lens microcartridge is illustrated in Figs. 40-43.

A deformable intraocular lens 234 is loaded on top of the receiver portion 206 of the lens holder portion 202. The deformable intraocular lens 234 is forced downwardly in the center thereof by implement or finger tip to reach the configuration shown in Fig. 42. The deformable intraocular lens is further pushed into the receiver  
5 portion 206 until it is fully inserted in the oval shaped configuration shown in Fig. 43 with its outer surface wrapping around and in contact with the sides 224, bottom 228, and top 226 of the receiver portion 206. The grooves defined by surfaces 226 hold the lens in position and guide it while the lens is being pushed through the microcartridge by the insertion instrument.

10

The edges of the deformable intraocular lens 234 contact with the downwardly extending protrusion 230 in the top 226, and ride along the protrusion 230 when being inserted through the lens microcartridge gently further folding the lens as it enters into the nozzle portion 204.

15

An alternative nozzle portion 204' is shown in Figure 44 having a beveled end. A further alternative nozzle portion 204'' is shown in Figure 45 having a heat deformed tip with a beveled end. Specifically, the end of the nozzle is heated and stretch to reach the shape and configuration shown.

20

## METHODS OF IMPLANTATION

The surgical procedure begins by coating the lens with a surgically compatible lubricant, and loading the lens into the microcartridge. For example, as shown in Figure 21, a lens 54 having a lens body 56, a leading haptic 58a is load into the microcartridge 12 while a trailing haptic 58b remains trailing outside the microcartridge in the manner shown. Specifically, the lens 54 is loaded downwardly into the opened microcartridge 12 until it sits on the inner surfaces of the tubular portions 74 and 78, for example, with a pair of tweezers. The outer circumferential surface of the lens 54 are held by edges 88 and 90 of the tubular portions 74 and 78, respectively. The rear edge of the lens 54 is placed approximately at the rear edge of the microcartridge 12. The lens 54 is further manipulated to situate the haptics 58a and 58b in the manner shown. Specifically, haptic 54a is positioned in a leading position and the other haptic 54b is positioned in a trailing position outside with respect to the direction of implantation, as indicated by the arrow.

Subsequently, the split tubular member 66 of the microcartridge 12 is closed about the lens 54 by forcing the extensions 76 and 80 together with his or her finger tips. The inner surfaces of the tubular portions 74 and 78 bend and fold the lens 54 when the extensions 76 and 80 are forced together, as shown in Figures 22 and 23. Due to the resilient nature of the deformable intraocular lens 54, the lens 54 conform

to the curved inner surface of the tubular portions 74 and 78 without damage thereto, as shown in Figure 23.

5 The microcartridge 12 containing the loaded lens 54 is inserted between the edges 17a, 17a of the opening 17 into the receiver 15 of the holder 13. As the microcartridge 12 is moved forward, the extensions 76 and 80 move past the tapered edges 17b and come to a stop position between the clamping edges 17c when front portions of the extensions 76 and 80 contact with the stop edge 17d. The clamping edges 17c prevent rotation of the microcartridge inside the holder 13.

10

The user pushes the threaded end cap 18 forward while securing the holder body 14 from movement, forcing the plunger 16 forward within the holder. As the plunger 16 is moved forward, the tip 20 enters into the rear of the microcartridge 12 and misses the trailing haptic 58B until the tip makes contact with the loaded lens 54, as shown in Figure 24. As the plunger 16 is moved forward in this manner, the lens 54 previously lubricated, is forced into the implantation nozzle 68 of the microcartridge 12, as shown in Figure 25.

15

Once the lens 54 enters the implantation nozzle 68, the threads of the end cap 18 contact with the threads of the sleeve 24 stopping further movement of the plunger 14 forward in this manner. The end cap 18 is slightly rotated to engage the threads of the end cap 18 with the threads of the sleeve 24. At this point, the surgical device is

20

ready for the implantation step. The nozzle is insert through the incision in the eye, and the end cap 18 is rotated to continue the forward movement of the plunger 16 by continued rotation of the end cap 18 relative to the holder body 14 to expel the lens from the nozzle into the interior of the eye, as shown in Figure 26. This manner of  
5 screw advancement for moving the plunger 16 forward provides for precise control and accuracy concerning forcing the lens 54 through the remaining portion of the tip 68 into the eye during the implantation procedure. The deformed lens after exiting the nozzle 16 returns to its original configuration, full size and fixed focal length.

10 After the lens is inserted into the eye, the end cap 18 is further rotated to fully expose the tip 20 of the plunger 16, as shown in Figures 28 and 29, to allow the lens to be pushed forward, side manipulated to rotate the lens, and pushed down to properly position the lens within the eye without the aid of other surgical instruments.

15 The configuration of the tip 20 is important during the implantation process. The faceted tip 20 provides a clearance between the tip 20 and the inner surface of the passageway through the microcartridge 12 to accommodate the trailing haptic 58b during movement of the lens within the microcartridge 12, as shown in Figures 25 and 26. Specifically, there exists a sufficient clearance between the flat surface facet 44  
20 and the inner wall of the passageway through the microcartridge 12. During the implantation process, the trailing haptic floats around in the space between the extension 42 of the tip 20 and the inner wall of the passageway, as shown in Figure 25.

This prevents any chance of damage to the trailing haptic, for example, by being caught between the tip 20 and the lens 54 during the implantation process. The leading haptic moves through the passageway unimpeded during the implantation process preventing any damage thereto.

5

### FLAT LOADING LENS CARTRIDGE

Another preferred embodiment of a cartridge 300 is shown in Figures 46 to 51.

10

The cartridge 300 is a contoured duct apparatus for curling and inserting a flexible intraocular lens into an eye with low radial pressure. The cartridge 300 is defined by a generally tubular body 302 provided with a longitudinally disposed lens-curling duct 304 having a lens inlet end 306 and lens outlet end 308 for insertion into an eye. The lens inlet end 306 and lens outlet end 308 are connected by a pair of mutually opposed converging longitudinal lens-engaging grooves 310 for guiding opposing edge portions of the lens towards one another with low radial pressure to a curled position as the lens is advanced through the duct 304 from the inlet end 306 to the outlet end 308.

15

20

The cartridge 300 can be configured to load in the injecting device shown in Figure 1. The plunger 16 of the injecting device provides means for advancing the lens through the duct 304 of the cartridge 300 from the inlet end 306 to the outlet end 308.

The lens inlet end 306 is an elongated transverse aperture having a major axis, and wherein proximal ends of the lens engaging grooves 310 are disposed at opposing ends of the major axis to slidably engage diametrically opposed peripheral edge portions of the lens. The opposing longitudinal grooves 310 include portions 310a that  
5 converge from the lens inlet end 306 to the lens outlet end 308.

The lens outlet end 306 can have an oval cross-sectional shape, as shown in Figure 51, or alternatively can have a generally circular transverse aperture. Further, the inlet end 306 and the outlet end 308 are coaxially aligned along a longitudinal axis  
10 of the duct. The means for advancing the lens is a coaxially aligned plunger 16 of the injecting device shown in Figure 1 longitudinally disposed within the tubular body during lens injection, and provided with a lens engaging tip 20. The lens engaging tip 20 is provided with a lens haptic receiving relief.

15 The cartridge 300 is defined by a lens holding portion 312 and a nozzle portion 314. The nozzle portion 314 can act the same as or equivalent to a curled lens insertion cannula that is disposed in coaxial lens conducting communication with the lens outlet end 308. The tubular body 302 is provided with a lens receiving chamber 316 disposed adjacent to the lens inlet end 306. In addition, the lens receiving chamber  
20 316 is provided with a slot 318 or peripheral lens emitting opening.



## FUNNEL TYPE CARTRIDGE

A further embodiment of a cartridge 400 shown in Figures 52 to 57.

5           The cartridge 400 is defined by a generally tubular body 402 provided with a longitudinally disposed lens-curling duct 404 having a longitudinal axis, an inlet end 406 with a transverse major axis, and generally circular outlet end 408 longitudinally aligned with said inlet end 406. The duct 404 includes a pair of mutually opposed lens engaging grooves 410 with proximal ends disposed at opposite ends of said major axis  
10           and diametrically opposed peripheral edges of the lens. The pair of mutually opposed lens engaging and guiding grooves 410 converge toward the outlet end 408 and terminate above a plane determined by the perpendicular intersecting of the inlet major axis with the duct longitudinal axis. A lens chamber 412 is disposed adjacent to the inlet end 406 provided with a peripheral slot 414 or peripheral opening for access to  
15           the interior of the chamber 412.

          The cartridge 400 can be loaded in the injecting device shown in Figure 1. The plunger 16 of the injecting device is longitudinally disposed within the tubular body 402 during lens injection, and is aligned coaxially with the longitudinal axis of the lens-curling duct 404.  
20

The cartridge 400 is defined by a lens holding portion 416 and a nozzle portion 418. The nozzle portion 418 can function equivalent to a cannula coaxially aligned with the duct 404.

**I CLAIM:**

1. A contoured duct apparatus for curling and inserting a flexible intraocular lens into an eye with low radial pressure, said apparatus comprising:

5       a generally tubular body provided with a longitudinally disposed lens curling duct having a lens inlet end and an outlet end for insertion into an eye, said lens inlet end and outlet end connected by a pair of mutually opposing converging longitudinal lens-engaging grooves for guiding opposing edge portions of said lens toward one another with low radial pressure to a curled position as said lens is advanced through  
10       said duct from said inlet end to said outlet end; and

          means for advancing said lens through said duct from said inlet end through said outlet end.

2. The apparatus of claim 1 wherein said duct inlet end is an elongated  
15       transverse aperture having a major axis and wherein proximal ends of said lens engaging grooves are disposed at opposing ends of said major axis to slidingly engage diametrically opposed peripheral edge portions of said lens, said opposing longitudinal grooves converging from said inlet end to said outlet end toward one another and to a position above said major axis.

20

3. The apparatus of Claim 1 wherein said outlet is a generally circular transverse aperture.

4. The apparatus of Claim 1 wherein said inlet end and said outlet end are coaxially aligned along a longitudinal axis of said duct.

5. The apparatus of Claim 4 wherein said means for advancing is a coaxially aligned plunger longitudinally disposed within said tubular body and provided with a lens engaging tip.

6. The apparatus of Claim 5 wherein said lens engaging tip is provided with a lens haptic receiving relief.

10

7. The apparatus of Claim 1 further comprising a curled lens insertion cannula disposed in coaxial lens conducting communication with said outlet end.

8. The apparatus of Claim 1 wherein said tubular body is provided with a lens receiving chamber disposed adjacent to said duct inlet end.

15

9. The apparatus of Claim 8 wherein said lens-receiving chamber is provided with a peripheral lens admitting opening.

10. An apparatus for inserting a flexible intraocular lens into the eye, said apparatus comprising:

20

a generally tubular body provided with a longitudinally disposed lens-curling duct having a longitudinal axis, an inlet end with a transverse major axis, and a generally circular outlet end longitudinally aligned with said inlet end, said duct having a pair of mutually opposed lens engaging grooves with proximal ends disposed at opposite ends of said major axis and dimensioned to engage and guide diametrically opposed peripheral edges of said lens, said pair of mutually opposed lens engaging and guiding grooves converging toward said outlet and terminating above the plane determined by the perpendicular intersecting of said inlet major axis with said duct longitudinal axis;

10 a lens receiving chamber disposed adjacent to said duct inlet and provided with a peripheral opening for access to the interior of said chamber;

a plunger longitudinally disposed within said tubular body and aligned coaxially with the longitudinal axis of said lens-curling duct; and

a cannula coaxially aligned with said duct at said duct outlet.

15

11. The apparatus of Claim 10 wherein said plunger is provided with a lens-engaging tip having a lens haptic receiving relief.

12. The apparatus of Claim 10 wherein said cannula is detachably mounted to said lens-curling duct adjacent to said duct outlet.

20

13. A method for inserting a flexible intraocular lens into an eye with low radial pressure, said method comprising the steps of:

loading an uncurled lens into an apparatus having a lens curling duct internally configured with converging grooves for guiding opposing peripheral edges of said lens toward one another with low radial pressure from a duct inlet to a duct outlet to form a curled reduced lens shape capable of passing through a minimal incision in the eye;

inserting said duct outlet into said incision; and advancing said lens through the lens curling duct of the apparatus and out of the duct outlet into the eye.

14. The method of Claim 13, wherein said loading step includes introducing said lens into a receiving chamber adjacent to said lens-curling duct.

15. The method of Claim 14 wherein said advancing step includes displacing a plunger longitudinally along the interior of the apparatus from said receiving chamber through said lens-curling duct.

16. The method of Claim 15 wherein said advancing step includes displacing said plunger through a cannula extension of said outlet.

17. The method of Claim 13 wherein said inserting step comprises inserting a cannula extension of said outlet into said incision.

18. A deformable intraocular lens injection system, comprising:

an injecting device having a lens receiver and a movable plunger disposed therein, said injecting device including a passageway having at least one groove for manipulating the deformable intraocular lens.

5

19. A system according to Claim 18, wherein said at least one groove is configured for folding the deformable intraocular lens.

20. A system according to Claim 19, wherein said at least one groove is defined by a pair of opposed grooves for gripping edges of the deformable intraocular lens.

10

21. A system according to Claim 18, wherein said at least one groove is a downwardly tapering groove.

15

22. A system according to Claim 18, wherein said injecting device comprises a cartridge holding device and a lens cartridge.

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23. A system according to Claim 22, wherein said cartridge holding device and said lens cartridge are separate components.

24. A system according to Claim 23, wherein said cartridge is defined by a lens holding portion and a nozzle portion.



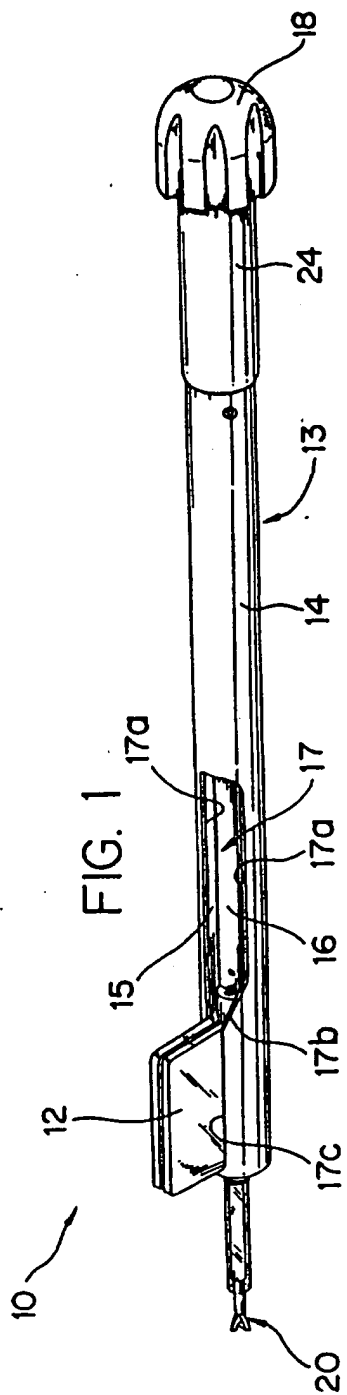


FIG. 1

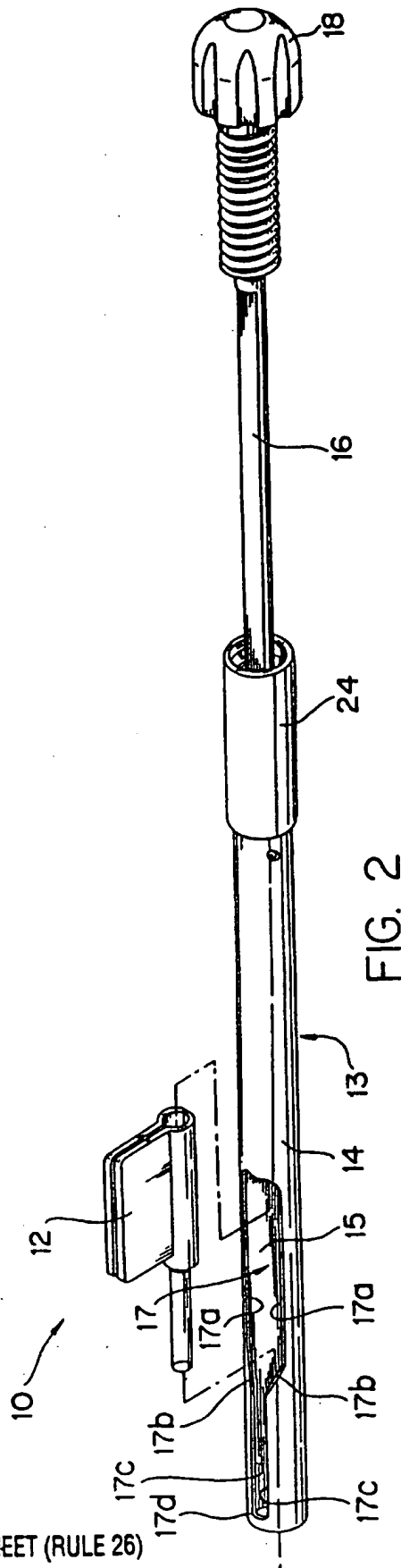
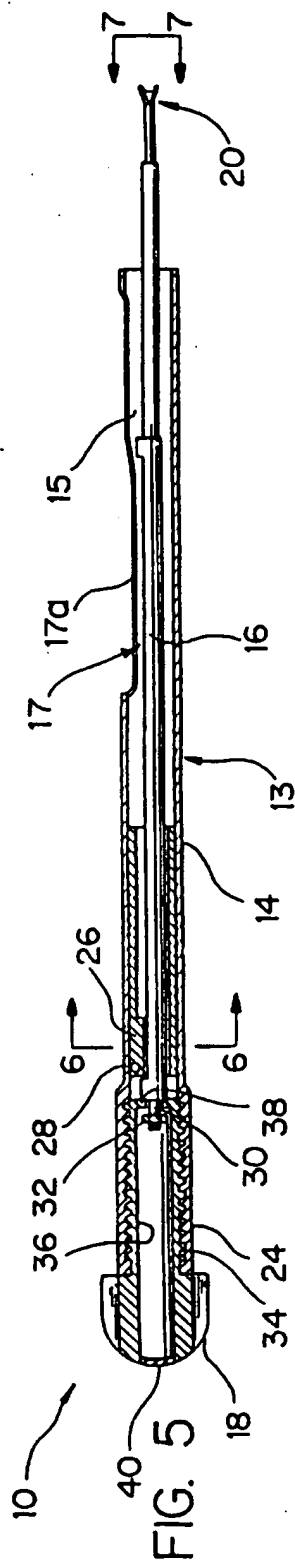
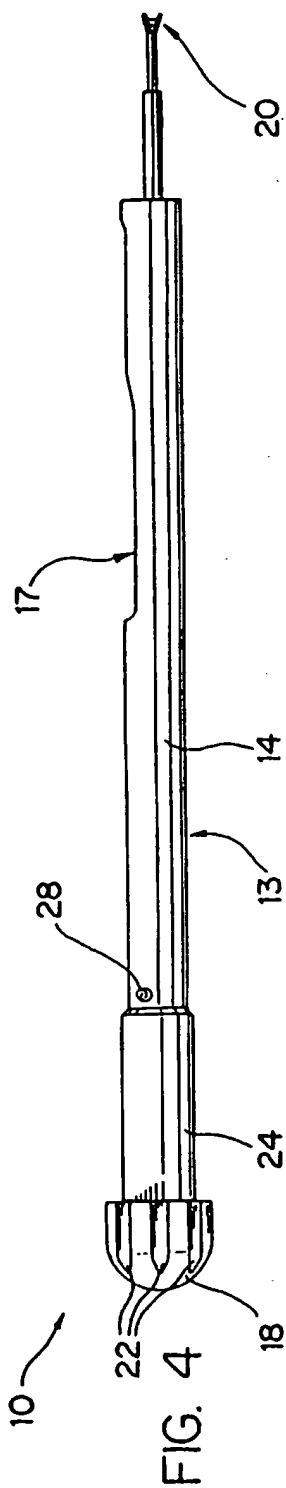
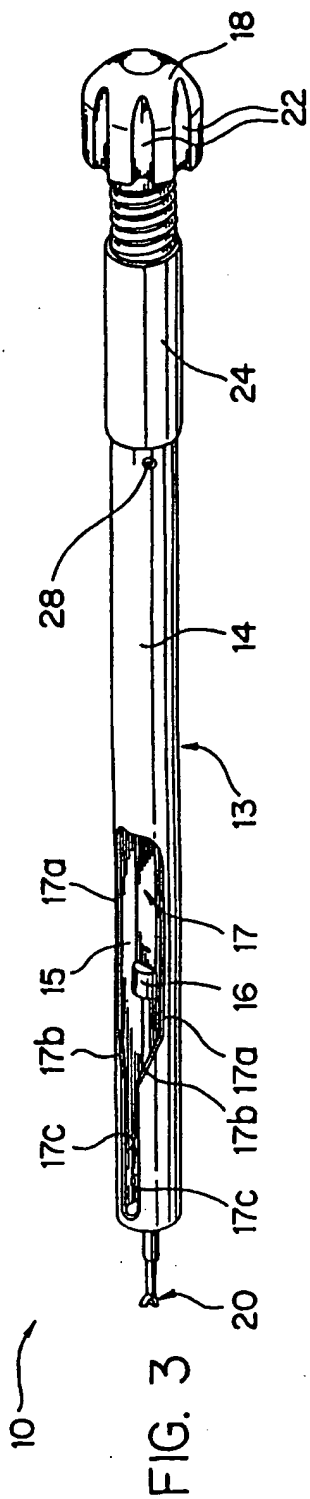


FIG. 2



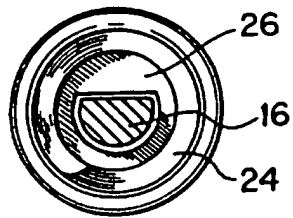


FIG. 6

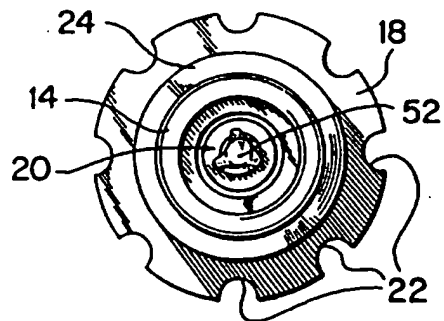


FIG. 7

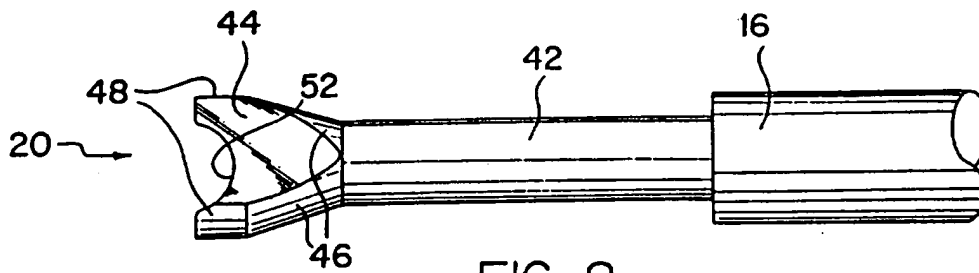


FIG. 8

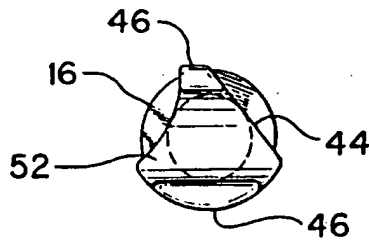


FIG. 9

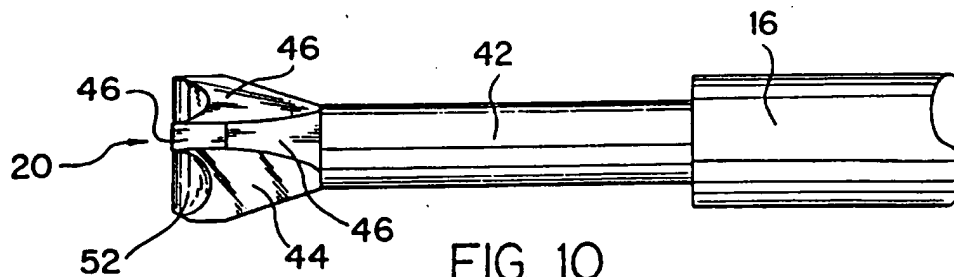
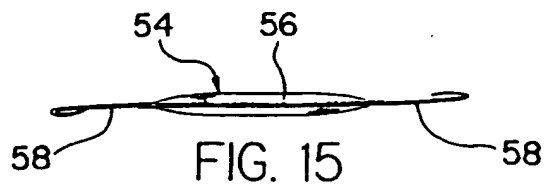
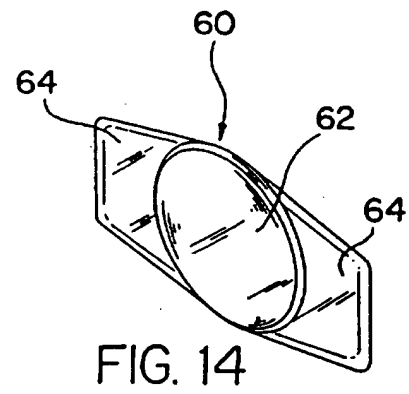
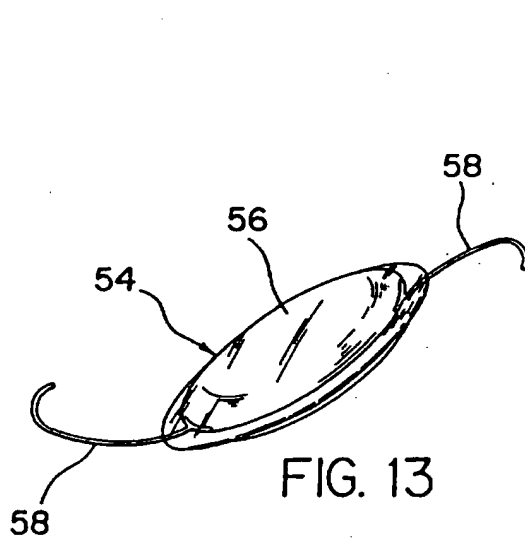
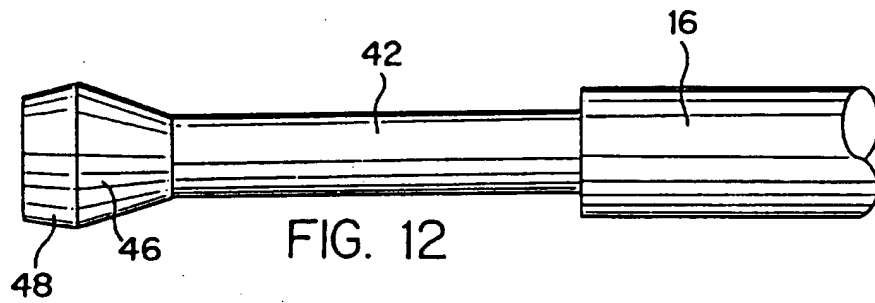
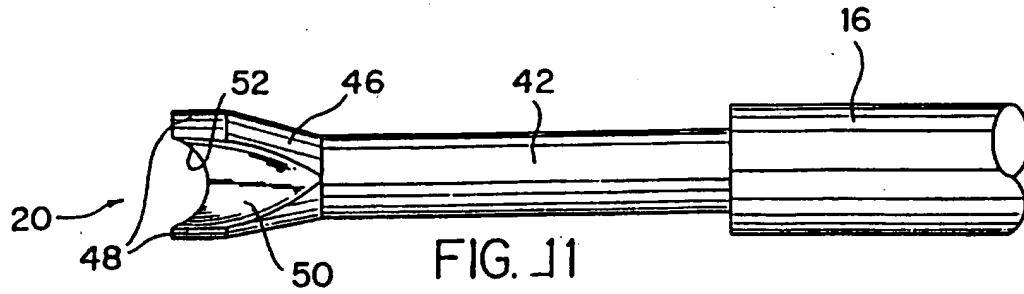
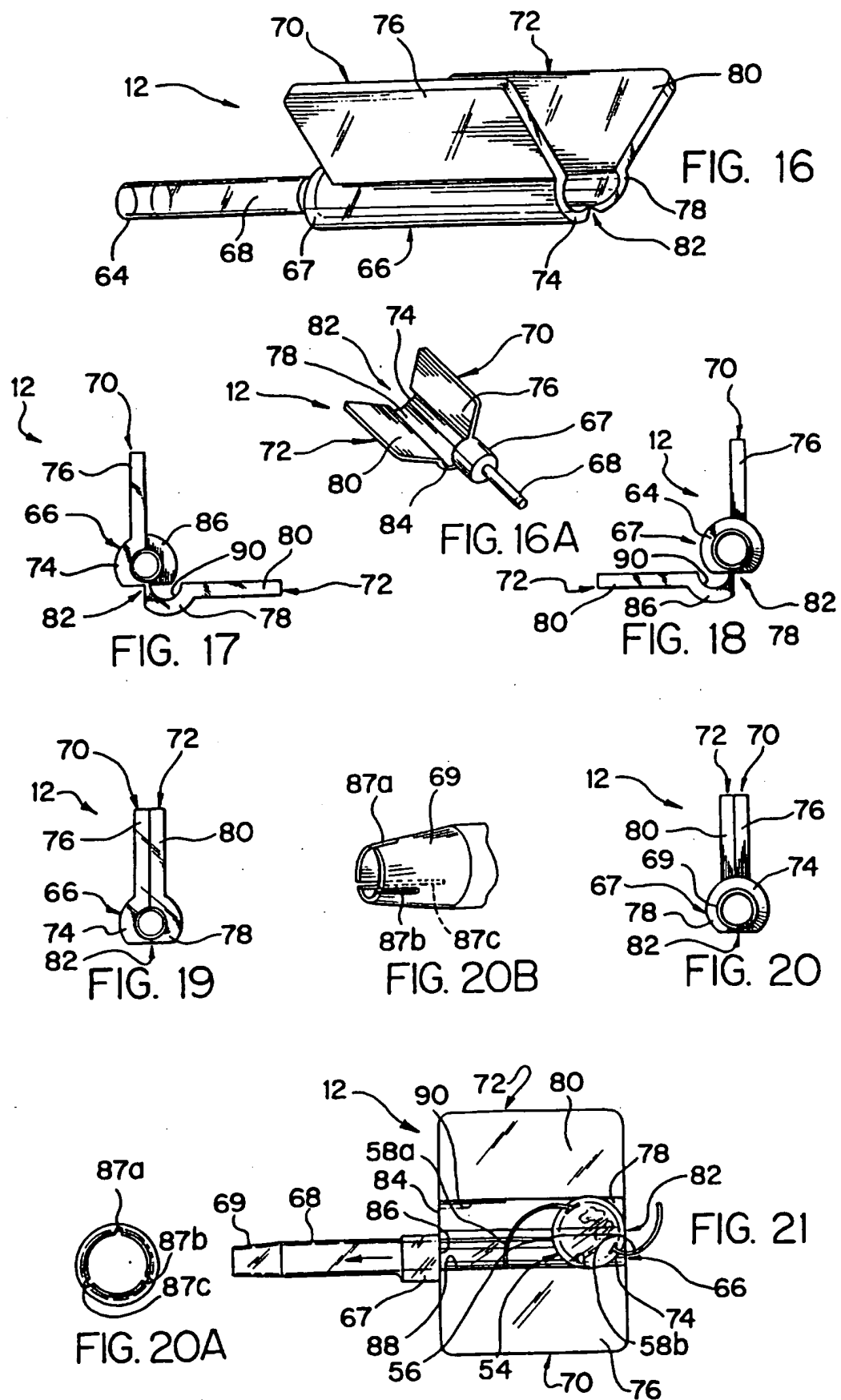
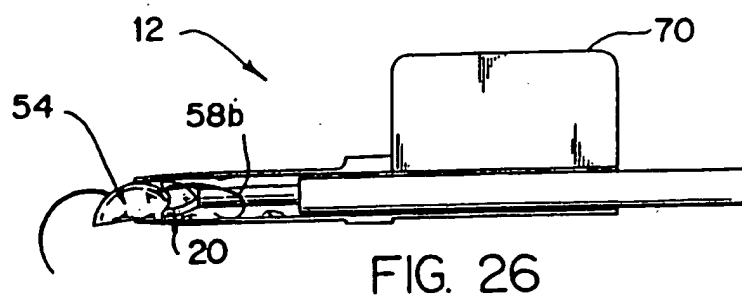
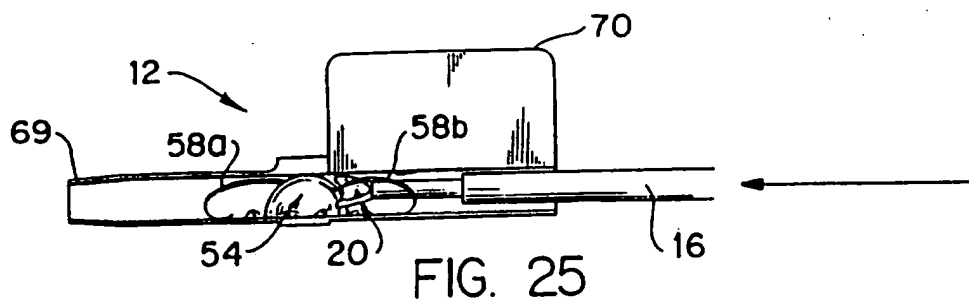
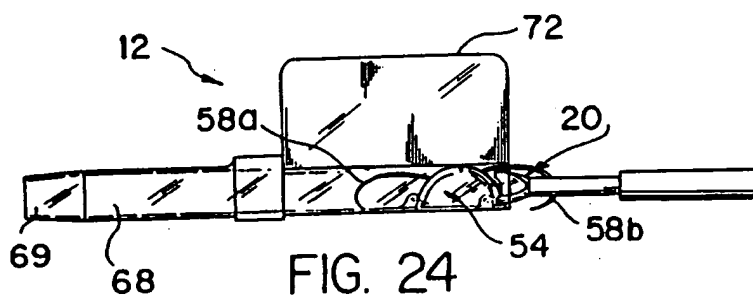
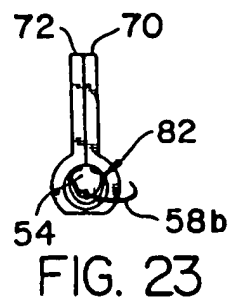
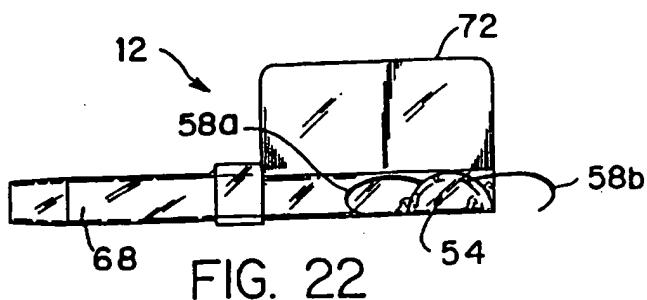


FIG. 10



5/12





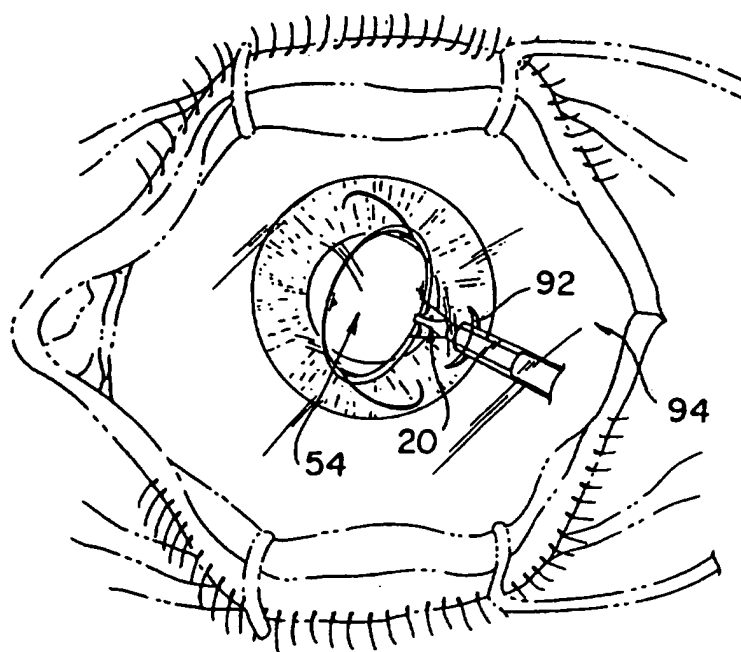


FIG. 27

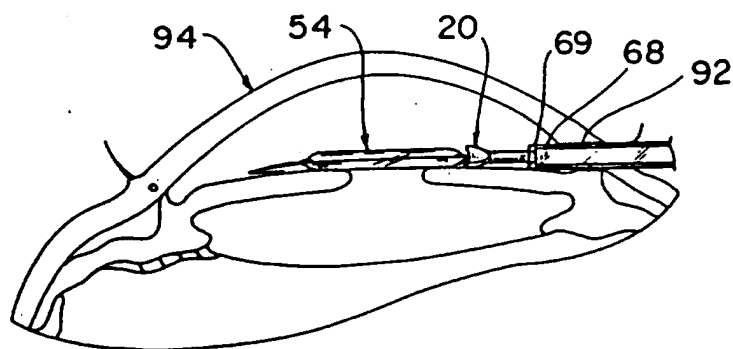


FIG. 28

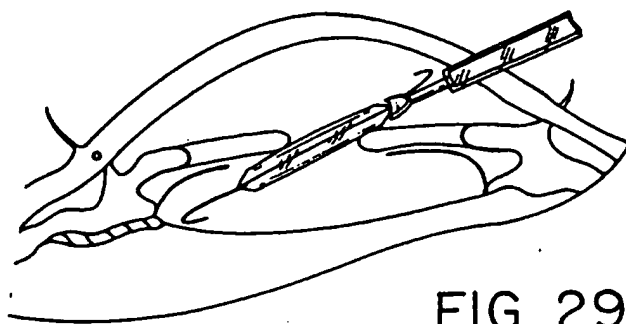


FIG. 29

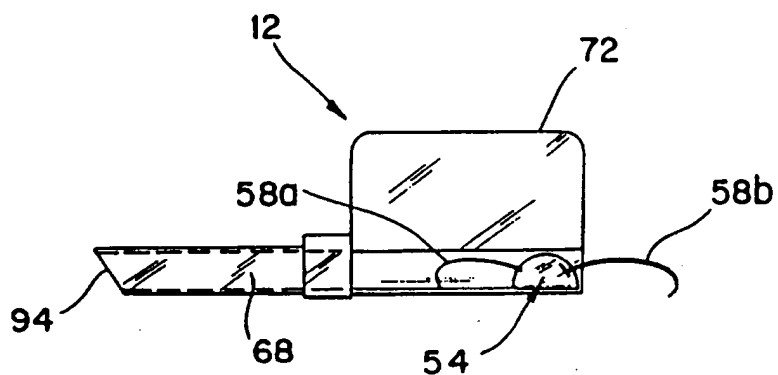


FIG. 30

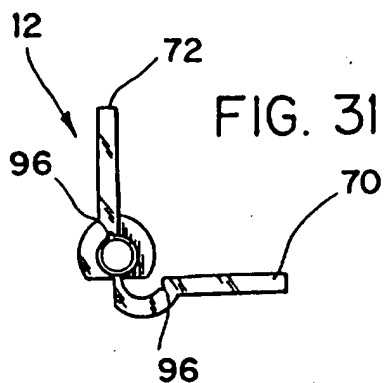


FIG. 31

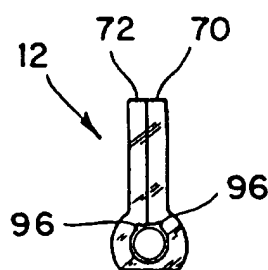


FIG. 32

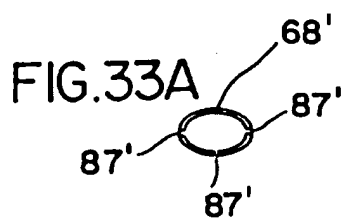


FIG. 33A

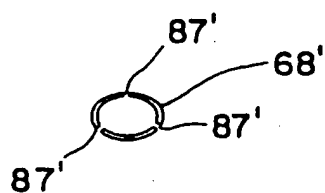


FIG. 33B



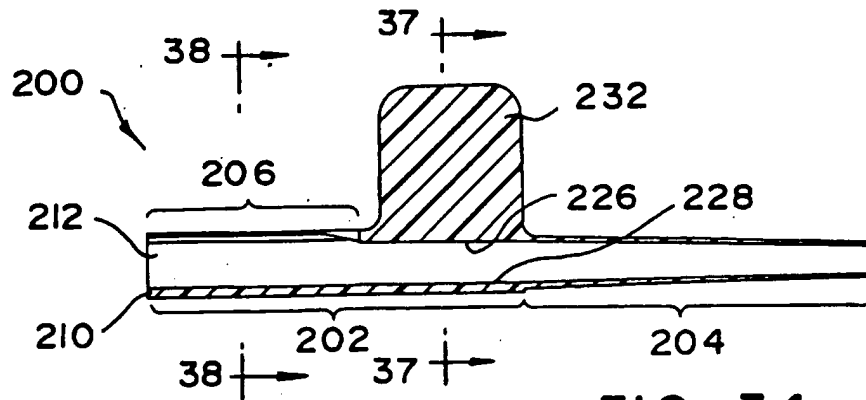


FIG. 34

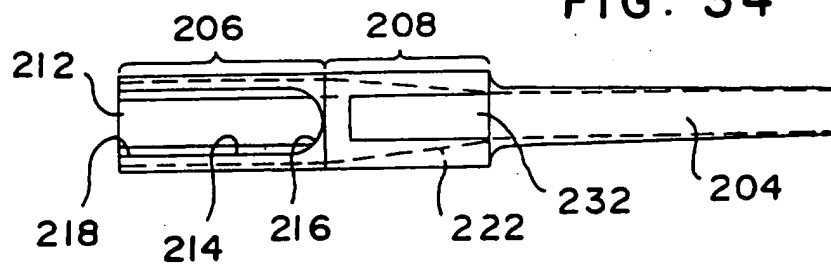


FIG. 35

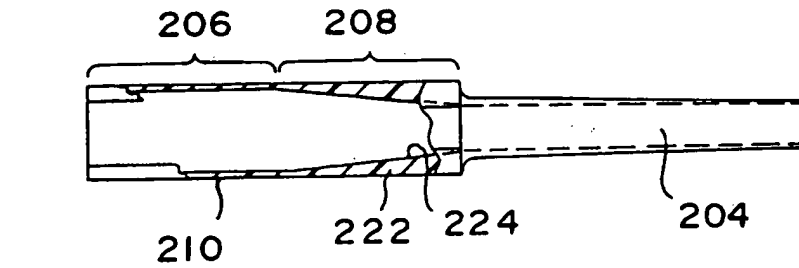


FIG. 36



FIG. 38

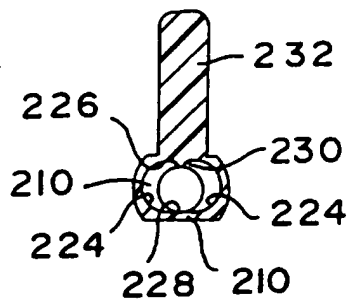


FIG. 37

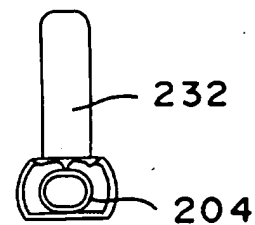


FIG. 39

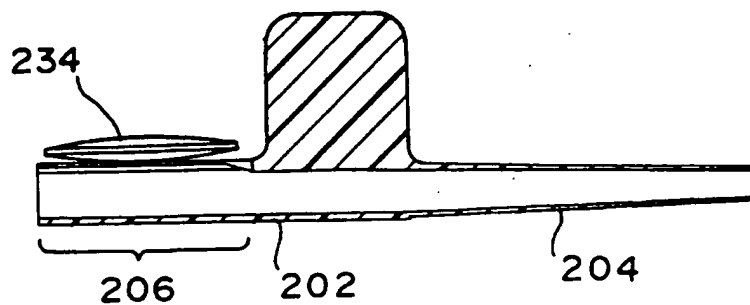


FIG. 40

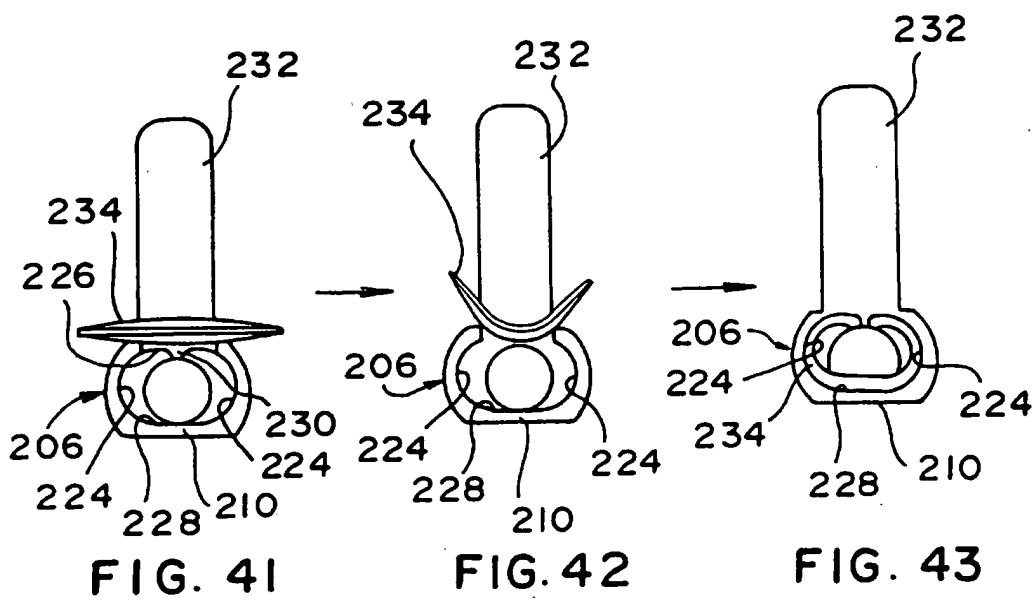


FIG. 41

FIG. 42

FIG. 43

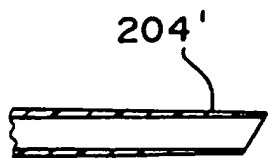


FIG. 44

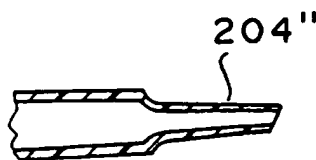
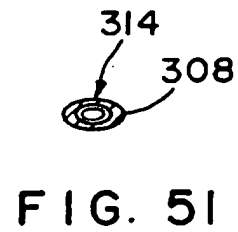
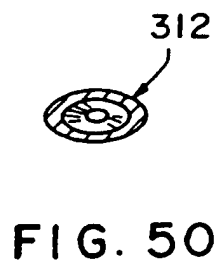
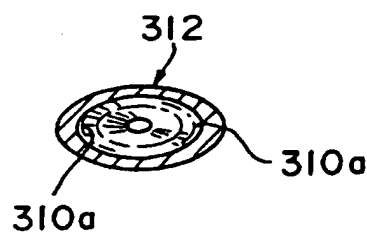
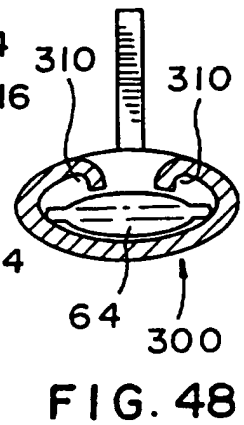
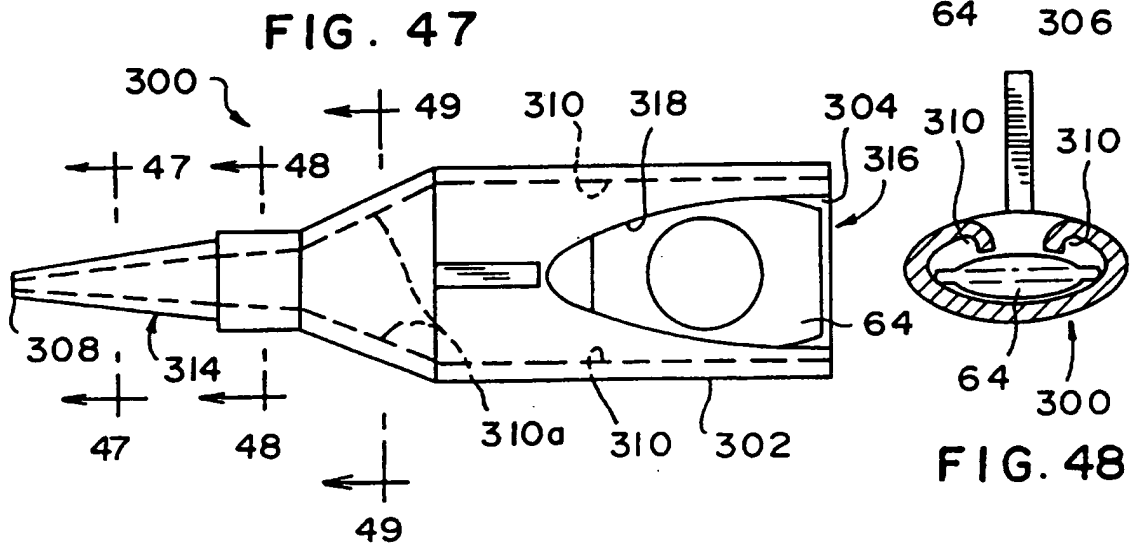
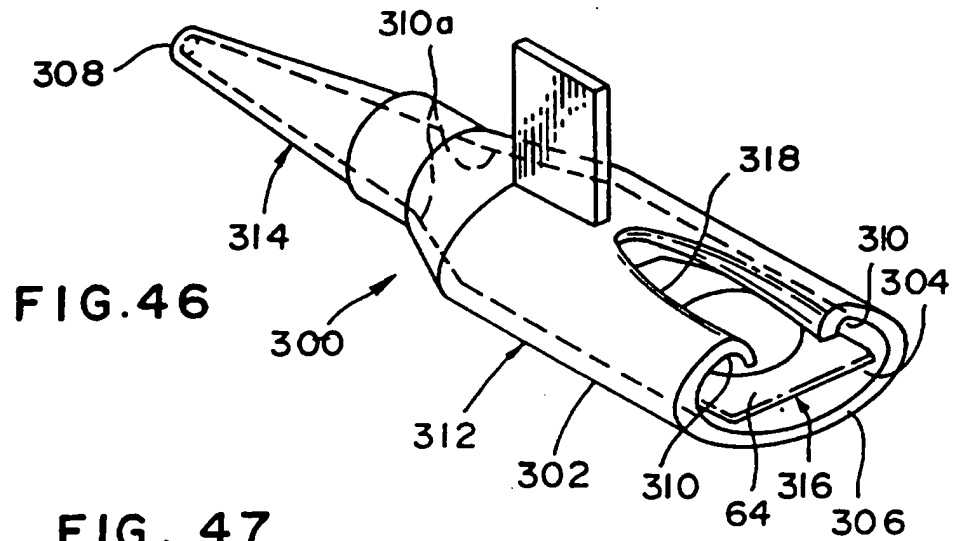


FIG. 45



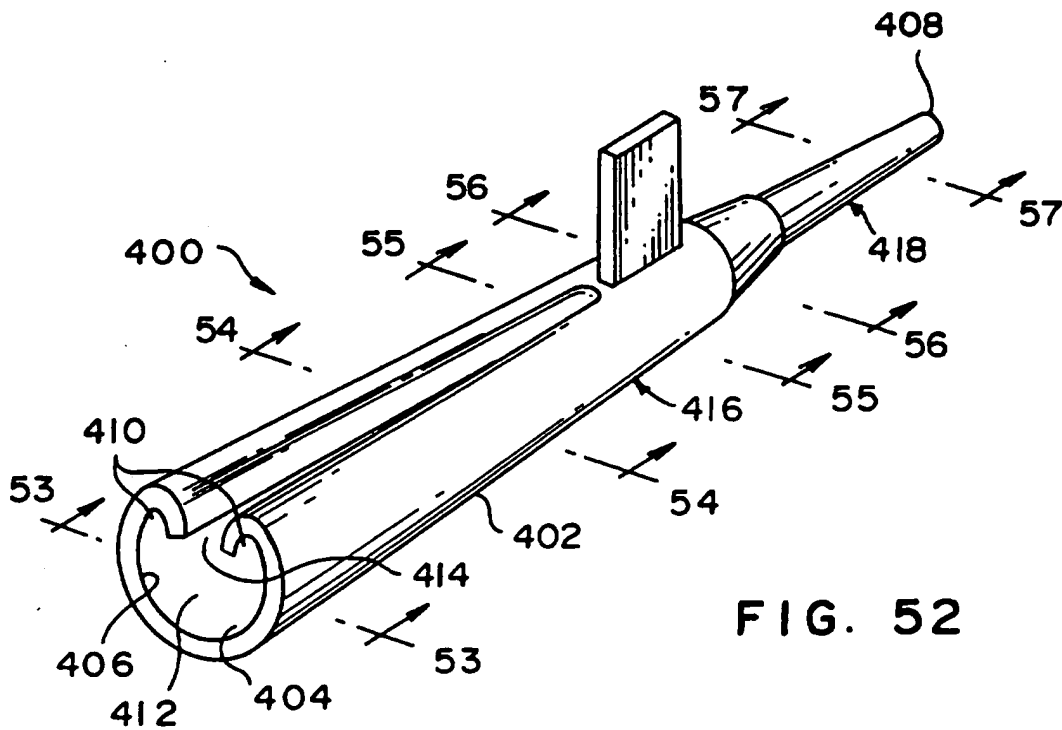


FIG. 52

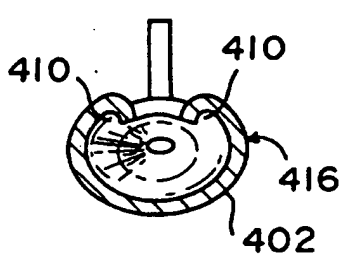


FIG. 53

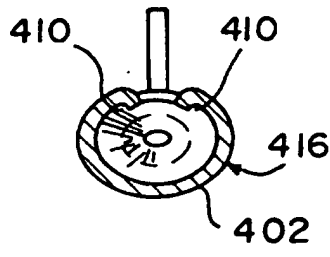


FIG. 54

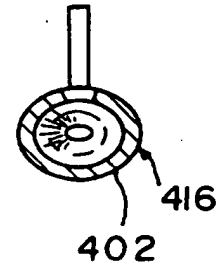


FIG. 55

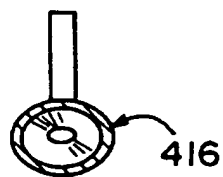


FIG. 56



FIG. 57

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/00264

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 9/00

US CL :606/107; 623/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/107; 623/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,275,604 (RHEINISH ET AL.) 07 January 1994, see entire document.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

22 MARCH 1996

Date of mailing of the international search report

11 APR 1996

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